REMARKS

Claims 1-7, 11 and 13-14 remain in this application. Claims 8-10, 12, and 15-16 have been canceled. New claims 17-19 have been added to provide more adequate coverage for applicant's contribution to the art.

New claim 17 further restricts present claim 1 by requiring that the three substantially spherical radiopaque markers are contiguous. New claim 18 further restricts present claim 13 by requiring that the three substantially spherical radiopaque markers are contiguous. New claim 19 further restricts present claim 14 by requiring that the three substantially spherical radiopaque markers are contiguous. New claims 17-19 are clearly supported by the original specification, particularly at page 15, line 22 to page 16, line 1; page 16, lines 22-24; and Fig. 10.

Applicant's invention provides a surgical sponge comprising a plurality of radiopaque markers having a high radiographic density and a distinctive, visually recognizable shape. The markers have an x-ray density equivalent to at least about 0.1 g/cm^2 of $BaSO_4$. The markers produce an x-ray image with high contrast and a shape that is readily recognizable and differentiated from the images produced by other items and structures commonly seen in x-rays of post-operative patients. Owing to the distinctive, high contrast image produced by the markers, the sponge is reliably and unambiguously detected. This is so even in situations where the sponge is inadvertently left in the surgical wound. Discomfort, trauma, and possibly fatal consequences that might otherwise occur are virtually eliminated. The surgical procedure is carried out with decreased likelihood of a sponge being retained inadvertently.

Claim Rejections – 35 USC § 103

The withdrawal of the rejection of applicant's claims based on U.S. Patent 3,736,935 to Reimels is noted with appreciation.

Claims 1-7 were rejected under 35 USC 103(a) as being unpatentable over Sirimanne et al. (US 6,371,904; hereinafter "Sirimanne").

Sirimanne discloses subcutaneous cavity marking devices and methods. More particularly, upon insertion into a body, the cavity marking device and method enable one to determine the center, orientation, and periphery of the cavity by radiographic, mammographic, echogenic, or other non-invasive imaging techniques. Also, the device contains a bioabsorbable or non-bioabsorbable marker. The device may be combined with various substances enhancing the radiopaque, mammographic, or echogenic characteristics of the marker or the body allowing it to be observed by any non-invasive imaging techniques. This is further a method of marking a subcutaneous cavity using a bioabsorbable material and a bioabsorbable or non-bioabsorbable marker in conjunction with the material. The method may additionally combine any of the features as described with the device.

Regarding claims 1-7, the Examiner has argued that Sirimanne teaches a surgical sponge (110) comprising three radiopaque markers (150, 154, 156), one of which (150) is a distinctive spherical shape, the markers (150, 154, 156)

disposed in a substantially fixed relationship (col. 7, lines 44-60; col. 8, lines 6-67)(see figs. 1D, 2A and 2B).

The Examiner has acknowledged that Sirimanne does not expressly disclose the specific X-ray density or size of the markers. However, the Examiner has argued that mere changes in size, weight or shape are not sufficient to patentably distinguish an invention over the prior art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" were held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was signficiant).

The Examiner has argued that, in the instant case, it is well known in the art that increased density and size of a barium marker increases its ability to be detected by an X-ray. (see, e.g., Dyer, US Pat. No. 4,639,253, col. 3, lines 4-12). Thus, the Examiner states that, at the time of the invention, it would have been

obvious to one of ordinary skill in the art to maximize the size and/or density of a barium sulfate marker in a surgical sponge in order to make it more readily detectable by an X-ray.

Applicant respectfully traverses these arguments and submits that the Examiner has not made out a *prima case* of obviousness. Applicant submits that present claims 1-7 clearly define over Sirimanne. Namely, claims 1-7, as amended, call for a surgical sponge comprising (i) three substantially spherical radiopaque markers; (ii) said markers being closely grouped to one another; (iii) each of said markers having an x-ray density equivalent to at least about 0.1 g/cm^2 of $BaSO_4$; and (iv) said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation.

Applicant respectfully submits that nowhere does Sirimanne disclose or suggest a surgical sponge comprising three substantially spherical radiopaque markers, the markers being closely grouped to one another. Instead, at Fig. 1D, Sirimanne discloses a surgical sponge having three radiopaque objects- only one of the objects (150) being substantially spherical. Further, the markers (150, 154, 156) at Fig. 1D of Sirimanne are not closely grouped to one another. See Sirimanne at col. 8, lines 6-18 which states:

"A trio of markers is also shown in FIG. 1D evenly aligned along the body longitudinal axis (140). Barb marker (156), spherical marker (150), and ring-shaped marker (154) demonstrate the use of different multiple markers in a single body (110). As previously described, such a design helps a physician to determine the spatial orientation of the inventive device when it is deployed in a biopsy cavity. Although the barb marker (156) is illustrated in a `V` configuration, it is an important aspect of the barb marker (156) to have a shape that is clearly not spherical. This allows the barb marker (156) to be easily distinguished from calcifications that may be observed during any non-invasive imaging techniques." (emphasis added).

Therefore, Sirimanne clearly teaches away from a sponge having three substantially spherical markers because Sirimanne discloses the need to have a barb marker (156) that is clearly not spherical in order to easily distinguish the marker from calcifications that may be observed during any non-invasive imaging techniques. Therefore, there is clearly no motivation to modify the three markers in Fig. 1D of Sirimanne so that each marker is substantially spherical. By way of contrast, the surgical sponge of present claims 1-7 comprises three substantially spherical markers that are closely grouped to one another, and therefore produce an x-ray image that is distinctive and easily recognizable. Therefore, even assuming arguendo that the three markers in Fig. 1D of Sirimanne were each modified to be substantially spherical, the markers would still not be closely grouped to one another, as required by present claims 1-7; and therefore the modified markers of Sirimanne would not be easily recognizable and might instead be mistaken for calcifications.

See, especially, Sirimanne at Fig. 1D which clearly shows the markers (150, 154, 156) being completely separate from each other. By way of comparison, present claims 1-7 require the markers to be closely grouped to one another, this result having the advantage of displaying an easily detectable image on an X-ray because of the grouping arrangement of the markers in close proximity to one another. Significantly, nowhere in the present Office Action is there even any mention of the limitation required by present claims 1-7 – "said markers being closely grouped to one another".

It is submitted that applicant's surgical sponges, as called for by present claims 1-7, are more readily discoverable by a radiologist viewing an X-ray of the patient's body because of there being three substantially spherical markers, the markers being closely grouped to one another, and disposed in a relationship that is substantially fixed both in spacing and in orientation.

Applicant further submits that the substantially spherical shape to the radiopaque markers is significant to the present invention, as claimed. Namely, as stated hereinabove, the substantially spherical configuration of the three closely grouped radiopaque markers allows them to be easily detected on an X-ray film taken of a patient. The substantially spherical shape is a preferred shape because a sphere has the same cross section view from all angles; therefore, no matter what the angle and/or configuration of the sponge when the patient is X-rayed, a spherical image will be easily recognized, especially when a close group of three substantially spherical markers are contained within the surgical sponge, as required by present claims 1-7, 11, 13-14, and 17-19.

Applicant respectfully submits that Sirimanne does not disclose these limitations, namely, three substantially spherical markers, the markers being closely grouped to one another. See arguments presented hereinabove. It is submitted that a *prima facie* case of obviousness has not been made out with respect to present claims 1-7.

Accordingly, reconsideration of the rejection of claim 1-7 under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne is respectfully requested.

Claim 11 was rejected under 35 USC § 103(a) as being unpatentable over Sirimanne as applied to claims 1-7 above, and further in view of Ishikawa et al. (US 6,366,206; hereinafter "Ishikawa").

Ishikawa el al. disclose a method and apparatus for attaching one or more transponders to medical and non-medical products to tag respective ones of the products with identifying data contained in a memory of the transponders. The one or more transponders each include a memory containing the corresponding identifying data which is emitted by the respective transponder in response to an electromagnetic signal emitted externally of the transponder. The identifying data corresponds to at least one of the respective one or more transponders and a respective product for tagging. The one or more transponders are attached to respective ones of the products to tag the products with the corresponding identifying data.

Regarding dependent claim 11, it is submitted that because this claim depends from independent claim 1, which applicant believes is patentable over Sirimanne for the aforementioned reasons, it is submitted that present claim 11 is patentable for the same reasons.

Further, applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. In particular, the Examiner has not pointed to any prior art reference that teaches or suggests the claimed combination of the two types of marking technologies, as called for by present claim 11. Instead, applicant submits that such combination is only found by hindsight reasoning and/or applicant's own disclosure. *See* MPEP 2142 *et seq.*

Accordingly, reconsideration of the rejection of claim 11 under 35 USC §103(a) as being unpatentable over Sirimanne in view of Ishikawa et al. is respectfully requested.

Claims 13 and 14 were rejected under 35 USC §103(a) as being unpatentable over Sirimanne as applied to claims 1-7 above, and further in view of *Uncommon Peril of Forgotten Surgical Tools*, Denise Grady, The New York Times, Jan. 21, 2003 (hereinafter "*Uncommon Peril*").

The Examiner acknowledges that Sirimanne does not disclose expressly disclose the steps of x-raying a patient and removing a surgical sponge thereafter. However, the Examiner states that *Uncommon Peril* teaches that a patient suspected of having a surgical sponge or other implement having a marker inside them can be x-rayed and if the implement is found to be there, it can be removed.

Applicant respectfully submits that present claims 13 and 14, as amended, patentably define over Sirimanne in view of *Uncommon Peril* – namely, because this combination of references does not disclose or suggest a method of detecting a surgical sponge within a surgical patient, said surgical sponge comprising three substantially spherical radiopaque markers, said markers being closely grouped to one another, each of said markers having an x-ray density equivalent to at least about 0.1 g/cm^2 of $BaSO_4$, said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation, and said method comprising the steps of: (a) obtaining at least one x-ray of at least a

portion of said patient likely to contain said radiopaque markers; and (b) examining said x-ray to detect and locate an image of said sponge.

Accordingly, reconsideration of the rejection of claims 13 and 14 under 35 USC §103(a) as being unpatentable over Sirmanne in view of Uncommon Peril is respectfully requested.

Further regarding new claims 17-19, these claims clearly define over the applied art because these claims further require that the three substantially spherical radiopaque markers be contiguous. "Contiguous" is defined as "being in actual contact : touching along a boundary or at a point". See Merriam-Webster's Medical Dictionary. Merriam-Webster, Inc. 27 Feb. 2007. <Dictionary.com http://dictionary.reference.com/browse/contiguous>. Clearly, none of the applied references disclose or suggest a sponge having three contiguous substantially spherical radiopaque markers.

Applicant's invention, as defined by present claims 1-7, 11, 13-14, and 17-19 discloses a surgical sponge comprising three substantially spherical radiopaque markers, the markers being closely grouped to one another. Advantageously, this allows for a distinctive, visually recognizable shape in any direction when the sponge is exposed to an X-ray machine, since the imprint of the three closely grouped spheres is detectable in any direction.

The surgical sponge disclosed by present claims 1-7, 11, 13-14, and 17-19 includes three closely grouped substantially spherical radiopaque markers – making their detection instantly recognizable, and does not even require the

careful scrutiny of a trained radiologist to detect. This "signature" created by the grouping of three substantially spherical markers is an instantly recognizable indication that there is a retained sponge inside the patient. By way of comparison, the radiopaque markers taught by the prior art can easily be overlooked or even mistaken for something else because they do not consist of a unique shape or design. Therefore, unlike the prior art surgical sponges, applicant's surgical sponge, as defined by present claims 1-7, 11, 13-14, and 17-19 is readily detectable.

CONCLUSION

In view of the amendments to the claims and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the rejection of present claims 1-7, 11, and 13-14, and their allowance, together with new claims 17-19, are earnestly solicited.

Respectfully submitted,
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